REMARKS

Claims 47 and 48 have been cancelled. Hence, Claims 33-46 and 49 remain active and under consideration.

REQUEST FOR RECONSIDERATION

As noted previously, claims 33-46 and 49 provide a vaccine for immunizing fish against ciliated ectoparasitic protozoans containing an effective amount of a fusion protein expressed from a recombinant DNA sequence for immobilization antigen, repeat I of *Ichthyophthirius multifiliis*, wherein the fusion protein is at least one selected from the group consisting of SEQ. ID Nos. 1-17.

> The vaccine of present Claim 33 has an important characteristic that a synthetic, i.e., recombinant, gene is used to express the fusion protein in the vaccine. That is, the fusion protein of Claim 33 is expressed from a recombinant gene which affords a modified protein. Further, the recombinant gene used to express fusion protein may be expressed by any organism, such as yeast, baculovirus in insect cells, and even transgenic plants and animals. See page 6 of the present specification.

Further, although a portion of the fusion protein of the claimed vaccine is arguably similar to a portion of the predicted protein product of Clark et al., Clark et al. neither disclose nor suggest that only a portion of their predicted protein could be

used functionally as an antigen, thereby enabling the preparation of a vaccine. They also fail to either disclose or suggest which portion of their predicted protein would be so used.

This is an important and unexpected development inasmuch as prior to the present invention, no vaccine against *Ichthyophthirius multifiliis* was available, and moreover, conventional *in vitro* systems had proven unsuccessful in yielding a useful vaccine. See page 3 of the present specification.

In the Advisory Action of November 3, 2005, the Examiner maintains that all of the arguments advanced for patentability pertain to the process of making the presently claimed vaccine composition. However, this is respectfully not true.

It is true that, Clark et al. merely describe the cloning of a ciliate, *Ichthyophthirius multifiliis*, cDNA and conclude that the cDNA encodes a surface antigen. Although, the authors do mention the potential of the antigen as a protective immunogen as a general statement in the "Discussion" section, there is neither a description nor a suggestion in Clark et al. as to how the antigen could be produced. This clearly suggests the unobviousness of the present vaccine composition in and of itself.

Further, the immunogen hypothesized by Clark et al. was based on their published native cDNA encoding 394 amino acids. The only conceivable way to obtain any antigen based upon this publication would be to purify the antigen protein from the ciliate

Ichthyophthirius multifiliis. However, as the material supply is so limited, this approach is very impractical. See page 3 of the present specification.

In contrast, by virtue of the present invention, a synthetic (recombinant) gene is used to prepare the fusion protein antigen of the vaccine of present Claims 33-46 and 49. Notably, the synthetic (recombinant) gene arguably contains only, at best, a portion of the predicted protein of Clark et al., yet it has been demonstrated experimentally that this relatively short peptide is functional as a protective immunogen. Thus, the vaccine of present Claims 33-46 and 49 includes, at best, only a portion of the predicted protein product of Clark et al.; however, it is completely functional as an antigen and can be made very practically. Thus, the fusion protein of the claimed vaccine is different from the predicted protein of Clark et al.

In summary, and for emphasis, the following distinctions are made between the present vaccine of Claim 33-46 and 49, and Clark et al.

First, Clark et al. merely speculate that the predicted protein product of their published native cDNA sequence (encoding 394 amino acids) might be used as an antigen against *Ichthyophthirius multifiliis*. However, Clark et al. neither disclose nor suggest that any portion of this predicted protein would function as such an antigen. This clearly implies the

unobviousness of the present invention as noted above.

Second, Clark et al. only speculate that their predicted protein (based upon their published native cDNA sequence) might function as an antigen against *Ichthyophthirius multifiliis*. No suggestion or guidance is provided for actually preparing a vaccine based on the actual protein or any portion thereof.

Third, the present inventors have found, unexpectedly, that only a portion of the entire predicted protein of Clark et al. in a fusion protein is sufficient to prepare a functional antigen against *Ichthyophthirius multifiliis*. Further, the present inventors have actually evidenced the effectiveness of a vaccine containing this fusion protein in challenge tests. See page 14-19 of the present specification containing the fusion protein.

It is this latter point, in particular, that the Examiner has failed to acknowledge, let alone address. Specifically, it is asked how the presently claimed vaccine composition could be obvious when the fusion protein contained therein includes only a portion of a protein which is merely predicted by Clark et al.? For example, Clark et al. provides no guidance, motivation or enablement to isolate only a portion (and which portion?) of its predicted protein. Further, Clark et al. afford no reasonable expectation of success in making the presently claimed vaccine.

Finally, Clark et al. fail to either disclose or suggest: 1) how to construct the synthetic or recombinant gene of the present

invention (See pages 10-11 of the present in contrast), and 2) how to express and purify the fusion protein of the present invention (See pages 11-14 of the present application), and 3) how to prepare and use a vaccine containing the fusion protein. Moreover, pages 14-19 of the present specification will demonstrate the effectiveness of the claimed vaccine.

Furthermore, the vaccine of Claims 33-46 and 49 is effective not only against *Ichthyrophthirius multifiliis* but also against other ciliated ectoparasitic protozoans. This result is neither disclosed nor suggested by Clark et al.

It is axiomatic that a cited reference must be enabling in order to raise a question of anticipation or obviousness. In re O'Farrell, 7 U.S.P.Q. 2d 1673 (Fed. Cir. 1988). Specifically, the isolation of a protein cannot be obvious without enablement. Ex parte Maizel, 27 U.S.P.Q. 2d 1662 (Bd. Pat. App. & Intl. 1992). Even more so in the present case, Applicants: 1) use only at best a portion of a predicted protein (which was never made or isolated by Clark et al.), 2) to prepare a fusion protein, which is then 3) used in a vaccine, which is effective against ciliated ectroplasmic protozoans.

Thus, at least three levels of enablement are missing in Clark et al.: 1) the isolation of a protein fragment, 2) the preparation of a fusion protein, and 3) the preparation and use of a vaccine against ciliated ectroplasmic protozoans.

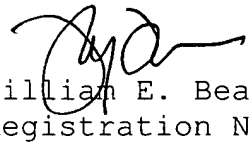
Clearly, one skilled in the art would be neither motivated nor enabled by Clark et al. to make and use the vaccine of present Claim 33. Most certainly, one skilled in the art would not be put in possession of the vaccine of present Claim 33 from Clark et al.

It is respectfully urged that upon reconsideration, the Examiner specifically address the structural differences between the presently claimed vaccine composition and the predicted protein of Clark et al. as elucidated above.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 07-1337 and please credit any excess fees to such deposit account.

Respectfully submitted,

LOWE HAUPTMAN & BERNER, LLP



William E. Beaumont
Registration No. 30,996

Customer Number: 22429
1700 Diagonal Road, Suite 300
Alexandria, Virginia 22314
(703) 684-1111 **WEB/sj**
(703) 518-5499 Facsimile
Date: **November 21, 2005**